

DEPARTMENT OF HEALTH

NOTICE OF PROPOSED RULEMAKING

The Director of the Department of Health, pursuant to the authority set forth in section 302(14) of the District of Columbia Health Occupations Revision Act of 1985, effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code § 3-1203.02(14)), and Mayor's Order 98-140, dated August 20, 1998, hereby gives notice of his intent to take final rulemaking action to adopt the following amendment to Chapter 40 (Health Occupations: General Rules) of Title 17 (Business, Occupations & Professions) (May 1990) of the District of Columbia Municipal Regulations (DCMR) in not less than thirty (30) days from the date of publication of this notice in the *D.C. Register*. The purpose of the amendment is to clarify the period of time that a license is valid after the fee is paid.

Chapter 40 of Title 17 DCMR is amended as follows:**Section 4006.1 is amended to read as follows:**

- 4006.1 The term of a license, certificate, or registration issued or renewed pursuant to this subtitle shall be two (2) years or for the balance of the license period, whichever is shorter.

All persons desiring to comment on the subject matter of this proposed rulemaking should file comments in writing not later than thirty (30) days after the date of the publication of this notice in the *D.C. Register*. Comments should be sent to the Department of Health, Office of the General Counsel, 825 North Capitol Street, N.E., 4th Floor, Washington, D.C. 20002. Copies of the proposed rules may be obtained from the Department at the same address during the hours of 9:00 a.m. to 5:00 p.m., Monday through Friday, excluding holidays.

DEPARTMENT OF HEALTH

NOTICE OF PROPOSED RULEMAKING

The Director of the Department of Health, pursuant to the authority set forth under § 302(14) of the District of Columbia Health Occupations Revision Act of 1985 ("Act"), effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code § 3-1203.02 (14)), and Mayor's Order 98-140, dated August 20, 1998, hereby gives notice of his intent to take final rulemaking action to adopt the following amendments to Chapter 42 of Title 17 of the District of Columbia Municipal Regulations (DCMR) in not less than thirty (30) days from the date of publication of this notice in the D.C. Register.

The purpose of the amendments is: to amend the qualifications to administer general anesthesia, intravenous sedation, and nitrous oxide to include maintaining current certification in cardiopulmonary resuscitation for health care providers; to require dentists who administer any form of anesthesia under this chapter, including local anesthesia, to report to the Board of Dentistry any death, substantially disabling incident, or hospitalization caused by the administration of such anesthesia with thirty (30) days after the occurrence; to adopt a code of ethics for the practice of dentistry in the District of Columbia which includes following the Center for Disease Control's guidelines on infection control and universal precautions; and to clarify that a dentist whose dental license in another state is revoked, suspended, or otherwise not in good standing must bring that license into good standing before he or she will be eligible to apply for licensure in the District of Columbia.

The following rulemaking action is proposed:

17 DCMR Chapter 42, DENTISTRY, is amended to read as follows:

A new section 4203 is added to read as follows:**4203 DENTISTS LICENSED IN OTHER STATES**

4203.1 A dentist shall not be qualified to apply for initial licensure, reinstatement or renewal of licensure to practice in the District of Columbia if any dental license(s) he or she holds, or has ever held, in another state or jurisdiction(s) is revoked or suspended or otherwise not in good standing as determined by the Board, until such time as the dental license(s) is restored to good standing in the jurisdiction(s) where the disciplinary action(s) took place.

Section 4212 is amended to read as follows:**4212 REQUIREMENTS FOR ADMINISTRATION OF ANESTHESIA**

4212.1 To be qualified to administer general anesthesia, a dentist shall meet the following requirements prior to administering general anesthesia:

- (a) Hold an active license to practice dentistry in the District of Columbia;
- (b) Have obtained appropriate training as follows:
 - (1) Successfully complete a minimum of one (1) year of training in anesthesiology beyond the undergraduate dental school level or its equivalent, sponsored by an accredited hospital recognized by the Board or an institution recognized by the American Dental Association Commission on Dental Accreditation and approved by the Board;
 - (2) Be certified, or eligible to take the examination for certification as a fellow in general anesthesia of the American Society of Dental Anesthesiologists (ASDA) according to the standards as of January 1, 1982;
 - (3) Be a diplomate of the American Dental Society of Anesthesiology (ADSA) through the examination administered by the National Dental Board of Anesthesiology (NDBA);
 - (4) Be a diplomate of the American Board of Oral & Maxillofacial Surgery (ABOMS); or
 - (5) Be a fellow of the American Association of Oral & Maxillofacial Surgery (AAOMS), or successfully complete an oral and maxillofacial surgery training program approved by the American Dental Association (ADA);
- (c) Maintain current certification in cardiopulmonary resuscitation for health care providers as evidenced by a certificate;
- (c) Maintain current Drug Enforcement Administration ("DEA") and District of Columbia controlled substance registrations; and
- (d) Conspicuously display proof of meeting the requirements set forth in this section next to his or her dental license in any and all places of business or employment where he or she administers general anesthesia.

4212.2 To be qualified to administer intravenous sedation, a dentist shall meet the following requirements prior to administering intravenous sedation:

- (a) Hold an active license to practice dentistry in the District of Columbia;

- (b) Successfully complete a postgraduate training program or course sponsored by an accredited hospital recognized by the Board or institution recognized by the American Dental Association Commission on Dental Accreditation and approved by the Board, consisting of a minimum of sixty (60) hours of didactic instruction plus the management of at least twenty (20) patients per participant demonstrating competency and clinical experience in intravenous sedation;
- (c) Maintain current certification in cardiopulmonary resuscitation for health care providers as evidenced by a certificate;
- (d) Maintain current DEA and District of Columbia controlled substance registrations; and
- (e) Conspicuously display proof of meeting the requirements set forth in this section next to his or her dental license in any and all places of business or employment where he or she administers intravenous sedation.

4212.3 To be qualified to administer nitrous oxide alone, or nitrous oxide in combination with a single oral drug, a dentist shall meet the following requirements prior to administering nitrous oxide:

- (a) Hold an active license to practice dentistry in the District of Columbia;
- (b) Have successfully completed a training program or course in nitrous oxide consisting of a minimum of forty (40) hours of either undergraduate dental school or postgraduate instruction at an accredited institution recognized by the American Dental Association Commission on Dental Accreditation or in a program approved by the Board. This training shall include actual experience with the administration of nitrous oxide.
- (c) Maintain current certification in cardiopulmonary resuscitation for health care providers as evidenced by a certificate;
- (d) Maintain current DEA and District of Columbia controlled substance registrations; and
- (e) Conspicuously display proof of meeting the requirements set forth in this section next to his or her dental license in any and all places of business or employment where he or she administers nitrous oxide.

4212.4 A dentist who is qualified to administer general anesthesia pursuant to § 4212.1 of this chapter, shall be deemed qualified to administer intravenous sedation and nitrous oxide.

4212.5 A dentist who administers any form of anesthesia pursuant to this chapter, including local anesthesia, shall report to the Board any death, substantially disabling incident,

or hospitalization caused by the administration of any form of anesthesia, by the dentist or a dental hygienist authorized by the Board of Dentistry to administer local anesthesia and nitrous oxide acting under his supervision, within thirty (30) days after the occurrence.

Section 4213 is amended by adding sections 4213.6 through 4213.60 to read as follows:

- 4213.6 A dentist shall respect a patient's rights to self-determination and treat the patient according to the patient's desires, within the bounds of accepted treatment.
- 4213.7 A dentist shall inform a patient of the proposed treatment, and any reasonable alternatives, in a manner that allows the patient to become involved in treatment decisions.
- 4213.8 A dentist shall protect the confidentiality of patient records and maintain patient records in a manner consistent with the protection of the welfare of the patient and all applicable District of Columbia and federal laws.
- 4213.9 A dentist shall make every effort to refrain from harming the patient.
- 4213.10 A dentist shall keep his or her knowledge of dentistry and skills current while he or she is engaging in clinical practice of dentistry.
- 4213.11 A dentist shall know his or her own limitations and shall refer a patient to a specialist or other health care professional whenever the welfare of a patient will be safeguarded or advanced by utilizing those who have special skills, knowledge, and experience.
- 4213.12 A dentist shall seek consultation with a specialist or other health care professional, if possible, whenever it would be in the patient's best interest.
- 4213.13 When patients visit or are referred to specialists or consulting dentists for consultation:
- (a) The specialists or consulting dentists shall, upon completion of their care, return the patient, unless the patient expressly reveals a different preference, to the referring dentist or, if none, to the dentist of record for future care; and
 - (b) When there is no referring dentist, the specialists shall upon completion of their treatment, inform the patient when there is a need for further dental care.
- 4213.14 A dentist who is called upon to render a second opinion regarding a diagnosis or treatment plan recommended by a patient's treating dentist, shall not have a vested interest in that recommendation.

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- 4213.15 A dentist shall know when and under what circumstances delegation of patient care to auxiliaries is appropriate.
- 4213.16 A dentist shall only assign to qualified auxiliaries those duties which can be legally delegated.
- 4213.17 A dentist shall prescribe and supervise the patient care provided by all auxiliary personnel working under his or her direction.
- 4213.18 A dentist shall not practice dentistry while abusing or using controlled substances, alcohol, or any other chemical agents, which impair the ability to practice.
- 4213.19 A dentist shall urge chemically impaired colleagues to seek treatment, if possible.
- 4213.20 A dentist with first-hand knowledge that a colleague is practicing dentistry when impaired by controlled substances, alcohol, or any other chemical agents shall report such evidence to the professional assistance committee of a dental society or the Board of Dentistry.
- 4213.21 A dentist or auxiliary who contracts any disease, has a mental or physical impairment which affects his or her ability to safely practice, or becomes impaired in any way that might endanger patients or dental staff shall, with consultation and advice from a qualified physician or other authority, limit the activities of his or her practice to those areas that do not endanger patients or dental staff.
- 4213.22 A dentist who has been advised to limit the activities of his or her dental practice shall monitor the disease or impairment and make additional limitations to the activities of his or her dental practice as indicated.
- 4213.23 A dentist, regardless of his or her bloodborne pathogen status, shall immediately inform any patient who may have been exposed to blood or other potentially infectious material in the dental office of the need for post-exposure evaluation and follow-up and shall immediately refer the patient to a qualified health care practitioner who can provide post-exposure services.
- 4213.24 In the event of an exposure incident as discussed in § 4213.23, a dentist shall provide information concerning his or her own bloodborne pathogen status to the evaluating health care practitioner, if the dentist is the source of the possible exposure, and submit to testing that will assist in the evaluation of the patient. If a staff member or other third person not regulated by the District of Columbia Board of Dentistry is the source of the possible exposure, the dentist shall encourage that person to cooperate as needed for the patient's evaluation.
- 4213.25 Once a dentist has undertaken a course of treatment to provide services to a patient, the dentist shall not discontinue that treatment without first giving the patient adequate notice and the opportunity to obtain the services of another dentist and ensuring that the patient's oral health will not be jeopardized in the

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process.

- 4213.26 A dentist shall not engage in interpersonal relationships with patients that could impair his or her professional judgment or risk the possibility of exploiting the confidence placed in him or her by a patient.
- 4213.27 A dentist shall provide competent and timely delivery of dental care.
- 4213.28 A dentist shall conduct himself or herself in a professional manner.
- 4213.29 A dentist shall make the results and benefits of his or her research and development investigative efforts available to all when such are useful in safeguarding or promoting the health of the public.
- 4213.30 A dentist shall not use patents or copyrights to restrict research or practice.
- 4213.31 A dentist shall become familiar with the signs of abuse and neglect and report suspected cases to the proper authorities consistent with District of Columbia and federal laws.
- 4213.32 While dentists, in serving the public, may exercise reasonable discretion in selecting patients for their practices, a dentist shall not refuse to accept patients into their practice or deny dental service to patients because of the patient's race, creed, color, sex, national origin, or sexual preference.
- 4213.33 A dentist shall not refuse to provide treatment to an individual based solely on the fact that the individual is infected with Human Immunodeficiency Virus, Hepatitis B Virus, Hepatitis C Virus, or another bloodborne pathogen.
- 4213.34 A dentist shall make reasonable arrangements for the emergency care of his or her patients of record.
- 4213.35 A dentist shall, when consulted in an emergency by patients with whom he does not have an established patient-practitioner relationship, make reasonable arrangements for their emergency care. If treatment is provided, the dentist, upon completion of treatment, shall return the patient to his or her regular dentist unless the patient expressly reveals a different preference.
- 4213.36 A dentist shall report to the District of Columbia Board of Dentistry known instances of gross or continual faulty treatment by other dentists.
- 4213.37 A dentist shall inform patients of their present oral health status without making disparaging comments about prior services.
- 4213.38 When informing a patient of the status of his or her oral health, a dentist shall make comments that are truthful, informed and justifiable.

- 4213.39 A dentist issuing a public statement with respect to the profession shall believe as well as have a reasonable basis to believe that the comments made are true.
- 4213.40 A dentist may provide expert testimony when that testimony is essential to a just and fair disposition of a judicial or administrative action.
- 4213.41 A dentist shall not agree to a fee contingent upon the favorable outcome of the litigation in exchange for testifying as a dental expert.
- 4213.42 A dentist shall not accept or tender rebates or split fees.
- 4213.43 A dentist shall not represent the care being rendered, or that is needed, to a patient in a false or misleading manner.
- 4213.44 A dentist shall not remove amalgam restorations containing mercury from patients who are not allergic to mercury for the alleged purpose of removing toxic substances from the body, when such treatment is performed solely at the recommendation or suggestion of the dentist.
- 4213.45 A dentist shall not remove sound or serviceable amalgam restorations containing mercury, at the request of a patient who is not allergic to mercury, without first obtaining appropriate informed consent from the patient, which includes but is not limited to advising the patient that:
- (a) The National Institutes of Health has determined that there are no verifiable systemic health benefits resulting from the removal of mercury amalgam restorations; and
 - (b) The removal of sound or serviceable mercury amalgam restorations may significantly affect the integrity of the tooth.
- 4213.46 A dentist shall not represent that dental treatment or diagnostic techniques recommended or performed by the dentist have the capacity to diagnose, cure or alleviate diseases, infections or other conditions, when such representations are not based upon accepted scientific knowledge or research.
- 4213.47 A dentist shall not represent the fees being charged for providing care in a false or misleading manner.
- 4213.48 A dentist shall not increase a fee charged to a patient solely because the patient is covered under a dental benefits plan.
- 4213.49 A dentist shall not misrepresent treatment dates for the purpose of assisting a patient in obtaining benefits under a dental plan which benefits would otherwise be disallowed.

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- 4213.50 A dentist shall not misrepresent the dental procedures performed to receive a greater payment or reimbursement or to make a non-covered procedure appear to be a covered procedure.
- 4213.51 A dentist shall not recommend or perform unnecessary dental services or procedures.
- 4213.52 A dentist who presents educational or scientific information in an article, seminar or other program shall disclose to the readers or participants any monetary or other special interest the dentist may have with a company whose products are promoted or endorsed in the presentation. Disclosure shall be made in any promotional material and in the presentation itself.
- 4213.53 A dentist who, in the regular conduct of his or her practice, engages in or employs auxiliaries in the marketing or sale of products or procedures to his or her patients shall not exploit the trust inherent in the dentist-patient relationship for his or her own financial gain.
- 4213.54 A dentist shall not induce his or her patients to purchase products or undergo procedures by misrepresenting the product's value, the necessity of the procedure or the dentist's professional expertise in recommending the product or procedure.
- 4213.55 In the case of a health-related product used by or recommended by a dentist, it is not enough for the dentist to rely on the manufacturer's or distributor's representations about the product's safety and efficacy. The dentist shall inquire into the truth and accuracy of such claims and verify that they are founded on accepted scientific knowledge or research.
- 4213.56 A dentist shall disclose to his or her patients all relevant information the patient needs to make an informed purchase decision, including whether the product is available elsewhere and whether there are any financial incentives for the dentist to recommend the product that would not be evident to the patient.
- 4213.57 A dentist shall not advertise or solicit patients in any form of communication in a manner that is false or misleading in any material respect.
- 4213.58 A general dentist who wishes to announce the services available in his or her practice may announce the availability of those services but shall not express or imply specialization.
- 4213.59 A dentist shall not announce available services in any way that would be false or misleading in any material respect.

- 4213.60 A dentist shall follow the Center for Disease Control's (CDC) guidelines on infection control and on universal precautions as they may be amended or republished from time to time.
- 4213.61 A dentist shall not willfully harass, abuse, intimidate, insult, degrade, or humiliate a patient physically, verbally, or by any form of communication.

Section 4214.2 is amended to read as follows:

- 4214.2 Pursuant to § 201(f) of the Act, D.C. Official Code § 3-1202.01(f)(2001), the limitation under this section shall not apply to a dentist who is an employee of, or operating pursuant to a contract with, the District or federal government and/or who is supervising dental hygienists who are employed by or operating pursuant to a contract with the District or federal government.

Section 4299.1 is amended as follows:

The following terms with the ascribed meanings are added as follows:

Auxiliary- means a person who may perform dental supportive procedures authorized by District of Columbia law or regulations under the specified supervision of a licensed dentist.

Bloodborne pathogen- means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV).

Universal precautions- means blood and body fluid precautions as defined by the Center for Disease Control.

Passed a Regional Board- means that an applicant has earned a score of seventy-five (75%) in each discipline, clinical skill, procedure, or knowledge that is tested on the NERB examination using the internal weighting and scoring methods the NERB uses to score the NERB's examination of dentistry or dental hygiene as applicable.

All persons desiring to comment on the subject matter of this proposed rulemaking action shall submit written comments, not later than thirty (30) days after the date of publication of this notice in the D.C. Register, to the Department of Health, Office of the General Counsel, 825 North Capitol Street, N.E., 4th Floor, Washington, D.C. 20002. Copies of the proposed rules may be obtained between the hours of 9:00 a.m. and 5:00 p.m. at the address listed above.

DEPARTMENT OF HEALTH
NOTICE OF PROPOSED RULEMAKING

The Director of the Department of Health ("Department"), pursuant to § 307 of the District of AccessRx Act of 2004, effective May 18, 2004 (D.C. Law 15-164; D.C. Official Code § 48-833.07) (the Act), and Mayor's Order 2006-60, dated June 7, 2006, hereby gives notice of his intent to take final rulemaking action to adopt the following new chapter 18 of Title 22 of the District of Columbia Municipal Regulations (DCMR), entitled "Prescription Drug Marketing Costs," in not less than thirty (30) days from the date of publication of this notice in the D.C. Register. The adoption of Chapter 18, which had until now been reserved, is necessary to implement Title III of the Act, which requires manufacturers and labelers of prescription drugs in the District who engage in marketing in the District to report to the Department their prescription drug marketing costs.

The Director of the Department of Health previously caused a Notice of Proposed Rulemaking to be published in the D.C. Register on September 29, 2006 indicating his intent to adopt final rules in not less than thirty (30) days from the date of publication of the September 29, 2006 notice in the D.C. Register at 53 DCR 7879. Pharmaceutical Research and Manufacturers of America thereafter requested a fifteen (15) day extension of the comment period so that more meaningful comments could be submitted. The Director of the Department of Health then caused an Amended Notice of Proposed Rulemaking to be published in the D.C. Register on November 10, 2006 indicating an extension of the comment period through November 14, 2006 and intending no other changes to the proposed rules as indicated in the D.C. Register at 53 DCR 9221. Comments were received by the Department of Health on or before November 14, 2006 from the AARP District of Columbia, Biotechnology Industry Organization, Councilmember David A. Catania, and Pharmaceutical Research and Manufacturers of America. In analyzing the comments, the Director of the Department of Health has concluded that substantive changes should be made to the proposed rulemaking to address issues raised by the comments and by analysis of the comments. Those substantive changes are included in the attached Notice of Proposed Rulemaking. The attached Notice of Proposed Rulemaking supersedes the Notice of Proposed Rulemaking dated September 29, 2006 and the Amended Notice of Rulemaking dated November 10, 2006.

Chapter 18 (Prescription Drug Marketing Costs) of Title 22 (Public Health and Medicine) is added as follows:

1800 MANNER OF REPORTING AND FILING FEE

1800.1 Beginning July 1, 2007, each manufacturer or labeler of prescription drugs, directly or indirectly distributed for dispensation in the District, that employs, directs or utilizes marketing representatives in the District shall file the annual report required by section 302 of the Act ("annual report") in the form and manner provided by the Director.

1800.2 The annual report shall be filed with the Department by July 1st of each year and

shall contain, for the previous calendar year, all of the information required by the Act and be accompanied by payment of the required filing fee.

- 1800.3 Manufacturers and labelers shall use the date of the activity to assign a reporting period and where the activity spans between more than one reporting period the cost shall be prorated by each applicable reporting period.
- 1800.4 Manufacturer and labeler grant amounts shall be reported for the period in which the money is provided and are not required to be allocated over the life of the grant.
- 1800.5 For purposes of the annual report due July 1, 2007 only, manufacturers and labelers shall report the required information by quarters. If any or all of the data for the first three quarters of 2006 is not available, then the manufacturers and labelers may substitute an explanation of why the data is not available for the data itself.
- 1800.6 In conjunction with filing the required annual report, each manufacturer or labeler shall pay to the Department the required filing fee of two thousand five hundred dollars (\$2,500), by mailing a check, made out to "D.C. Treasurer," to District of Columbia Department of Health, Chief Financial Officer, 825 North Capitol Street, N.E., Room 5100, Washington, D.C. 20002.
- 1800.7 The Department may reduce the amount of the filing fee through rulemaking if the Department finds that its administrative costs are less than anticipated.

1801 CONTENT OF ANNUAL REPORT

- 1801.1 The annual report shall include the following information as it pertains to prescription drug marketing costs and activities expended by the manufacturer or labeler in the District in a form that provides the value, nature, purpose, and recipient of the expense:
- (a) All expenses associated with advertising, marketing, and direct promotion of prescription drugs through radio, television, magazines, newspapers, direct mail, and telephone communications as they pertain to District residents;
 - (b) With regard to all persons and entities licensed to provide health care in the District, including health care professionals and persons employed by them in the District, carriers licensed under Title 31 of the D.C. Official Code (Insurance and Securities), health plans and benefits managers, pharmacies, hospitals, nursing facilities, clinics, and other entities licensed to provide health care in the District, the following information:
 - (1) All expenses associated with educational or informational programs, materials, and seminars, and remuneration for promoting or participating

in educational or informational sessions, regardless of whether the manufacturer or labeler provides the educational or informational sessions or materials. This includes but is not limited to:

- (i) Support for independent or continuing medical education programs (IME or CME) to the extent of participation by such persons and entities, including payments to medical education companies;
 - (ii) Printing costs of patient education materials and disease management materials distributed to such persons and entities. Design and other production costs also must be reported for materials designed specifically for District users;
 - (iii) Payment of consulting fees and expenses directly or indirectly to such persons and entities, subject to exceptions in § 1801.2 of this chapter;
 - (iv) Payments made directly or indirectly to such persons and entities for participation in speakers' bureaus and honoraria or other payments for time while speaking at or attending meetings, lectures or conferences;
 - (v) Payments made directly or indirectly to such persons or entities for writing articles or publications;
 - (vi) Charitable grants, either directly or earmarked, to such persons and entities, even if unrestricted; and
 - (vii) Payments made directly or indirectly to such persons or entities in connection with market research surveys or other activities undertaken in support of developing advertising and/or marketing strategies.
- (2) All expenses associated with food, entertainment, gifts valued at more than \$25, and anything provided to a health care professional for less than market value;
- (3) All expenses associated with trips and travel; and
- (4) All expenses associated with product samples, except for samples that will be distributed free of charge to patients; and
- (c) The aggregate cost of, including all forms of payment to, all employees or contractors of the manufacturer or labeler who directly or indirectly engage in the advertising or promotional activities listed in paragraphs (a) and (b), limited to that portion of payment to the employees or contractors that pertains to activities within the District or to recipients of the advertising or

promotional activities who are residents of or are employed in the District.

- 1801.2 The following expenses are not subject to the reporting requirements of this chapter:
- (a) Marketing expenses of twenty-five dollars (\$25) or less per day and per health care provider or entity;
 - (b) Reasonable compensation and reimbursement for expenses in connection with a bona fide clinical trial of a new vaccine, therapy, treatment, or indication;
 - (c) Scholarships and reimbursement of expenses for attending a significant educational, scientific or policy-making conference or seminar of a national, regional, or specialty medical or other professional association if the recipient of the scholarship is chosen by the association sponsoring the conference or seminar; and
 - (d) Expenses associated with advertising and promotional activities purchased for a regional or national market that includes advertising in the District if the portion of the costs pertaining to or directed at the District or cannot be reasonably allocated, distinguished, determined or otherwise separated out.
- 1801.3 All costs reported in the annual report must be determined using Generally Accepted Accounting Principles (GAAP).
- 1801.4 Each manufacturer or labeler subject to the provisions of the Act shall, as part of its annual report:
- (a) Report the name and contact information of the individual responsible for the company's compliance with the provisions of this chapter, and accuracy of the annual report;
 - (b) Identify by name and position title the individual submitting the report; and
 - (c) Submit separately in conjunction with the filing of the report under § 1802.1, a wet signature certification that "under penalty of law the information contained in the report is to the best of his or her knowledge after due diligence to inquire about the truthfulness and accuracy of the report," and an acknowledgment that providing false information or omitting required information on the report is unlawful.
- 1801.5 The individual identified in § 1801.4(a) of this chapter shall be a member of senior management or senior level company official within the manufacturer's or labeler's company or corporate structure.

1802 SUBMISSION OF ANNUAL REPORT

- 1802.1 Each manufacturer or labeler subject to reporting under the Act, shall submit the required annual report to the Department in an electronic format that is satisfactory to the Director.
- 1802.2 For each gift which was provided during the reporting period, that meets the requirements for mandated reporting, the manufacturer or labeler shall provide the following information:
- (a) Name of manufacturer or labeler;
 - (b) Date of payment or gift;
 - (c) Name of recipient;
 - (d) Type of recipient (e.g., clinic, doctor, hospital, pharmacist, university, other prescriber, benefits manager, health plan, nursing facility, psychiatric hospital, other healthcare provider);
 - (e) Credentials of recipient, if applicable (e.g., APRN, DDS, MD, DO, DPM, DVM);
 - (f) Nature of payment (e.g., book, cash or check, donation, food, grant, lodging, transportation, samples);
 - (g) Primary purpose of payment (e.g., consulting, professional education, charitable grant, speaker fee or payment); and
 - (h) Monetary value of payment.
- 1802.3 For each advertising, marketing, or direct promotion activity which occurred during the reporting period, that meets the requirements for mandated reporting, the manufacturer or labeler shall provide the following information:
- (a) Name of manufacturer or labeler;
 - (b) Date(s) of activity;
 - (c) Type of activity (e.g., advertising, marketing, direct promotion, market research survey, patient education including materials such as disease management information; materials/consulting to promote new uses of drugs);
 - (d) Medium (e.g., radio, television, magazines, newspapers, direct mail, telephone);

- (e) Name of medium, if applicable (e.g., television or radio station, newspaper, magazine);
- (f) Product marketed (e.g., name of drug, general brand/company awareness);
- (g) Target audience (e.g., general public, prescribers); and
- (h) Cost of activity.

1802.4 For all employees and/or contractors of the manufacturer or labelers that that meets the requirements for mandated reporting, the manufacturer or labeler shall provide the aggregate costs, including all forms of payment, for these services as determined using GAAP.

1803 CONFIDENTIALITY AND PUBLIC INFORMATION

1803.1 Notwithstanding any provision of law to the contrary, information submitted to the Department pursuant to this title shall be confidential and not a public record.

1803.2 A manufacturer or labeler subject to reporting under the Act, as part of its annual report, may identify any information that it claims is a trade secret and if so identified, shall certify in writing the reasons for its claim that the information is a trade secret.

1803.3 Data compiled in aggregate form by the Department for purposes of the reporting required by the Act is a public record as long as it does not reveal trade information that is protected by District, state, or federal law.

1803.4 The Director shall designate a person to review the reports required in § 1805 of this chapter before publication of the reports to ensure against disclosure of a trade secret of any manufacturer or labeler that has filed a report in compliance with the Act and this chapter. As part of such determination, such person may contact the manufacturer or labeler.

1804 ENFORCEMENT AND FINE

1804.1 These rules may be enforced in a civil action brought by the Office of the Attorney General for the District of Columbia.

1804.2 Failure to timely file a complete annual report in accordance with the Act and the provisions of this chapter constitutes a civil violation.

1804.3 Each submission of false information or omission of required information on the annual report shall constitute a separate civil violation.

1804.4 A fine of one thousand dollars (\$1,000), plus costs and attorney's fees, may be adjudged for each civil violation.

- 1804.5 When a manufacturer or labeler fails to timely file a complete annual report in accordance with the Act and provisions of this chapter, the District's costs for enforcement shall include all costs expended by the Director and/or the Attorney General during the course of the investigation of noncompliance, subsequent enforcement and resolution of the enforcement action, including staff time, equipment use, hearing records, expert assistance, and such other items as the Department determines to be a cost of the action which shall be calculated at the higher of the actual costs or \$1000 per day for each day that the complete and accurate report was due but not filed.

1805 DEPARTMENT REPORTS

- 1805.1 Beginning November 30, 2007, the Department shall provide an annual report, providing information in aggregate form, on prescription drug marketing expenses, to the Council and the Attorney General by November 30th of each year.
- 1805.2 Beginning January 1, 2008, and every two (2) years thereafter, the Department shall provide a report to the Council and the Attorney General, providing information in aggregate form, containing an analysis of the data submitted to the Department, including the scope of prescription drug marketing activities and expenses and their effect on cost, utilization, and delivery of health care services, and any recommendations with regard to marketing activities of prescription drug manufacturers and labelers.

1899 DEFINITIONS

- 1899.1 As used in this Chapter the following terms shall have the meanings ascribed:

Act- AccessRx Act of 2004, effective May 18, 2004 (D.C. Law 15-164; D.C. Official Code § 48-831.01 et seq.)

Affiliate- any individuals, partnerships, corporations, joint ventures, companies, firms, contractors or other legal entities, if directly or indirectly, either one owns, controls or can control the other, or a third party owns, controls or can control both.

Council- Council of the District of Columbia

Department- Department of Health

Director- Director of the Department

Attorney General- Attorney General for the District of Columbia, formerly

known as the Corporation Counsel.

GAAP- Generally Accepted Accounting Principles. A widely accepted set of rules, conventions, standards, and procedures for reporting financial information.

Labeler- An entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 C.F.R. § 207.20.

Manufacturer- a manufacturer of prescription drugs and includes subsidiary or affiliate of a manufacturer.

Marketing Representative- an individual who is employed by or is under contract to represent a manufacturer or labeler and engages in the marketing of prescription drugs in the District to any person or entity licensed to provide health care in the District.

Trade secret- information, including a formula, pattern, compilation, program, device, method, technique, or process, that:

(A) Derives actual or potential independent economic value, from not being generally known to, and not being readily ascertainable by, proper means by another who can obtain economic value from its disclosure or use; and

(B) Is the subject of reasonable efforts to maintain its secrecy.

Wet signature- means a physically generated signature of a person that can be compared to other physically generated signatures of the person for verification of authenticity.

All persons desiring to comment on the subject matter of this proposed rulemaking action shall submit written comments, not later than thirty (30) days after the date of publication of this notice in the D.C. Register, to the Department of Health, Office of the General Counsel, 825 North Capitol Street, N.E., 4th Floor, Washington, D.C. 20002. Copies of the proposed rules may be obtained between the hours of 9:00 a.m. and 5:00 p.m. at the address listed above.

PUBLIC SERVICE COMMISSION OF THE DISTRICT OF COLUMBIA
1333 H STREET, N.W., SUITE 200, WEST TOWER
WASHINGTON, DC 20005

NOTICE OF PROPOSED RULEMAKING

FORMAL CASE NO. 1005, IN THE MATTER OF THE APPLICATION OF
VERIZON WASHINGTON, DC INC. TO RECLASSIFY BUSINESS DIAL TONE
LINE AND MESSAGE UNITS AS COMPETITIVE UNDER PRICE CAP PLAN
2004

1. The Public Service Commission of the District of Columbia ("Commission") hereby gives notice, pursuant to District of Columbia Official Code Section 2-505,¹ of its intent to act upon the Application of Verizon Washington, DC Inc. ("Verizon") to Reclassify Business Dial Tone Line and Message Units in not less than 60 days from the date of the publication of this Notice of Proposed Rulemaking ("NOPR") in the *D.C. Register*.²

2. On January 29, 2007, Verizon filed an application requesting reclassification of its Business Dial Tone Line and Message Units ("Business Services")³ as competitive services pursuant to Price Cap Plan 2004.⁴ Under Price Cap Plan 2004, Verizon's services are classified into four service baskets. Presently, Verizon's Business Services is classified as basic business services. Verizon states that because its Business Services is classified as a basic service, any tariff modification requires Commission approval which places Verizon at a competitive disadvantage in its ability to tailor or adjust its Business Services quickly and adeptly to meet the needs of its customers in the highly competitive District telecommunications market.⁵

¹ D. C. Official Code, § 2-505.

² *Formal Case No. 1005, In the Matter of Verizon Washington, D.C. Inc.'s Application to Reclassify Business Dial Tone Line and Message Units as Competitive Under Price Cap Plan 2004*, filed January 29, 2007 (Verizon's Application).

³ A business dial tone line is a telephone line used by business customers that connects the network interface to a telephone company's central office to be able to obtain local exchange service. A local exchange service is service which permits calling in the customer's local calling service area. A Message Unit is a unit of measurement by which the charges for certain local calls are ascertained.

⁴ *Formal Case No. 1005, In the Matter of Verizon Washington, D.C. Inc.'s Price Cap Plan 2004 for the Provision of Local Telecommunications Services in the District of Columbia*, Order No. 13370, rel. September 9, 2004.

⁵ Verizon's Application at 2.

3. The Commission notes that prices for basic residential, basic business, and discretionary services are regulated by the Commission pursuant to Price Cap Plan 2004. Prices for competitive services, however, are not regulated by the Commission.⁶ Accordingly, Verizon's request would remove existing price restrictions on these Business Services. Section 5(a) of Price Cap Plan 2004 requires the Commission to determine, no later than 60 days after the date of publication of the NOPR, that either the reclassification is approved, the reclassification is approved on an interim basis subject to the Commission completing its review, the reclassification is denied, or the reclassification request is held in abeyance because additional time is needed for the Commission to complete its review due to the complexity of the application.⁷

4. Verizon's Application is on file with the Commission and can be reviewed at the Office of the Commission Secretary, 1333 H Street, N.W., Suite 200, West Tower, Washington, D.C. 20005, between the hours of 9:00 a.m. and 5:30 p.m., Monday through Friday. Copies of the Application are available upon request, at a per-page reproduction cost.

5. Comments on Verizon's Application must be made in writing to Dorothy Wideman, Commission Secretary, at the above address. All initial comments must be received within 30 days of the date of publication of this NOPR in the *D.C. Register*. Persons wishing to file reply comments may do so no later than 40 days of the date of publication of this NOPR. After the comments have been received, the Commission will take final action on Verizon's Application as prescribed by Section 5(a) of Price Cap Plan 2004.

⁶ See Order No. 13370, ¶ 15.

⁷ See Price Cap Plan 2004 § 5(a).

DISTRICT OF COLUMBIA WATER AND SEWER AUTHORITY

NOTICE OF PROPOSED RULEMAKING

The Board of Directors of the District of Columbia Water and Sewer Authority ("the Board"), pursuant to the authority set forth in section 216 of the Water and Sewer Authority Establishment and Department of Public Works Reorganization Act of 1996, effective April 18, 1996 (D.C. Law 11-111, §§ 203(3), (11) and 216; D.C. Code §§ 34-2202.03(3), (11) and 34-2202.16, and Section 6(a) of the District of Columbia Administrative Procedure Act, approved October 21, 1968 (82 Stat. 1206; D.C. Code § 2-505(a), hereby gives notice of its intention to amend Chapter 1 of the Water and Sanitation Regulations to adopt: a new Right of Way / Pilot Fee. Final rulemaking action shall be taken in not less than thirty (30) days from the date of publication of this notice in the D.C. Register.

If the proposed rulemaking is adopted, the rules will replace existing rules adopted by the Board at its meeting of September 7, 2006. Final rulemaking action shall be taken in not less than thirty (30) days from the date of publication of this notice in the D.C. Register.

Comments on these proposed rules should be submitted, in writing, no later than thirty (30) days after the date of publication of this notice in the D.C. Register to, Linda R. Manley, Secretary to the Board, District of Columbia Water and Sewer Authority, 5000 Overlook Ave., S.W., Washington, D.C., 20032.

In addition, although not required the Board will also receive comments on this proposed fee at a public hearing to be held at a later date.

I. Timing of Final Action on Proposed Rulemaking

No final action will be taken on the Rulemaking Proposal described in this notice until after each of the following events has occurred:

1. A public hearing is held to receive comments on the proposed rulemaking. The hearing notice will be published in the District of Columbia Register when the hearing date is established.
2. The public comment period on this rulemaking expires; and
3. The Board of Directors takes final action after public comments are considered.

II. Rulemaking Proposal

The following rulemaking action is proposed:

Title 21 DCMR, Chapter 1 WATER SUPPLY, Section 112 FEES, subsection 112.5 RIGHT OF WAY OCCUPANCY FEE PASS THROUGH CHARGE is amended to read as follows:

112.5 RIGHT OF WAY OCCUPANCY FEE PASS THROUGH CHARGE / PILOT FEE-

The Right of Way Occupancy Fee Pass Through Charge / Pilot Fee, assessed to recover the cost of fees charged by the District of Columbia to the Water and Sewer Authority for use of District of Columbia public space and rights of ways, shall be as follows:

Effective October 1, 2007 the Right of Way Occupancy Fee Pass Through Charge / Pilot Fee of Forty-Four Cents (\$.44) for each One Hundred Cubic Feet (100ft³) of water used shall be increased to Forty-Seven Cents (\$.47) for each One Hundred Cubic Feet (100ft³) of water used.

DISTRICT OF COLUMBIA WATER AND SEWER AUTHORITY

NOTICE OF PROPOSED RULEMAKING

The Board of Directors of the District of Columbia Water and Sewer Authority ("the Board"), pursuant to the authority set forth in section 216 of the Water and Sewer Authority Establishment and Department of Public Works Reorganization Act of 1996, effective April 18, 1996 (D.C. Law 11-111, §§ 203(3), (11) and 216; D.C. Code §§ 34-2202.03(3), (11) and 34-2202.16, Section 6(a) of the District of Columbia Administrative Procedure Act, approved October 21, 1968 (82 Stat. 1206; D.C. Code § 2-505(a), and in accordance with 21 DCMR Chapter 40, hereby gives notice of its intention to amend Chapter 41 of the Water and Sanitation Regulations to adopt new retail water and sewer rates. Final rulemaking action shall be taken in not less than thirty (30) days from the date of publication of this notice in the D.C. Register.

If the proposed rulemaking is adopted, the rules will replace existing rules adopted by the Board at its meeting of September 7, 2006. Final rulemaking action shall be taken in not less than thirty (30) days from the date of publication of this notice in the D.C. Register.

Comments on these proposed rules should be submitted, in writing, no later than thirty (30) days after the date of publication of this notice in the D.C. Register to, Linda R. Manley, Secretary to the Board, District of Columbia Water and Sewer Authority, 5000 Overlook Ave., S.W., Washington, D.C., 20032.

In addition, the Board will also receive comments on these proposed rates at a public hearing to be held at a later date.

I. Timing of Final Action on Proposed Rulemaking

No final action will be taken on the Rulemaking Proposal described in this notice until after each of the following events has occurred:

1. A public hearing is held to receive comments on the proposed rulemaking. A hearing date will be determined at a later date, and will be published in the District of Columbia Register.
2. The public comment period on this rulemaking expires; and
3. The Board of Directors takes final action after public comments are considered.

II. Rulemaking Proposal

The following rulemaking action is proposed:

Title 21 DCMR, Chapter 41 RETAIL WATER AND SEWER RATES, Section 4100 RATES FOR WATER SERVICE, subsection 4100.3 is amended to read as follows:

CHAPTER 41 RETAIL WATER AND SEWER RATES

4100 RATES FOR WATER SERVICE

4100.3 The retail rate for metered water service of Two Dollars and Three Cents (\$2.03) for each One Hundred Cubic Feet (100ft³) of water used shall be:

- a) Effective October 1, 2007, increased from Two Dollars and Three Cents (\$2.03) for each One Hundred Cubic Feet (100ft³) of water used to Two Dollars and Eighteen Cents (\$2.18) for each One Hundred Cubic Feet (100ft³) of water used;

Title 21 DCMR, Chapter 41 RETAIL WATER AND SEWER RATES, Section 4101 RATES FOR SEWER SERVICE, subsection 4101.1 is amended to read as follows:

4101 RATES FOR SEWER SERVICE

4101.1 The retail rate for sanitary sewer service of Three Dollars and Six Cents (\$3.06) for each One Hundred Cubic Feet (100ft³) of water used shall be:

- a) Effective October 1, 2007, increased from Three Dollars and Six Cents (\$3.06) for each One Hundred Cubic Feet (100ft³) of water used, to Three Dollars and Twenty-Nine cents (\$3.29) for each One Hundred Cubic Feet (100ft³) of water used.

ZONING COMMISSION FOR THE DISTRICT OF COLUMBIA
NOTICE OF PROPOSED RULEMAKING
Z.C. CASE NO. 06-25
(Text and Map Amendment - Capitol Gateway Overlay District)

The Zoning Commission for the District of Columbia, pursuant to its authority under §§ 1 and 8 of the Zoning Act of 1938, approved June 20, 1938 (52 Stat. 797, as amended; D.C. Official Code §§ 6-641.01 and 6-641.07 (2001)), hereby gives notice of its intent to amend Chapters 16 of the Zoning Regulations (Title 11 DCMR). The proposed amendment to the Zoning Map would extend the boundaries of the Capitol Gateway ("CG") Overlay District to include Lot 48 within Square 649; those portions of Squares 651 and 653 zoned C-2-C; and Lots 124-140 within Square 655, adjacent to South Capitol Street S.W. Other than mapping the area within the CG Overlay, no changes to the base zones are recommended. The text amendments to §§ 1601, 1602, 1605, and 1610 would also:

- Require a setback 15-foot setback from South Capitol Street for any new development within Squares 653 and 655;
- Require that a minimum of 60% of the façade be constructed to the 15-foot setback line or to the property line where the setback is not required;
- Restrict driveway access from South Capitol Street;
- Establish a Zoning Commission review and approval process and design guidelines for any new development on property which abuts South Capitol Street; and
- Restrict the use of Combined Lot transfer of density to or from property within these squares.

Final rulemaking action shall be taken in not less than thirty (30) days from the date of publication of this notice in the *D.C. Register*.

The following rulemaking action is proposed:

Title 11 DCMR (Zoning), Chapter 16, CAPITOL GATEWAY OVERLAY DISTRICT, is amended as follows (new language is shown in bold and underlined text; deleted language in strikethrough):

A. Section 1600, PREAMBLE, subsection 1600.1, is amended to read as follows:

- 1600.1 The Capitol Gateway (CG) Overlay District is applied to the Buzzard Point and Capitol Gateway areas, which are designated for mixed use development in the Comprehensive Plan for the National Capital. The following Squares and portions of Squares in the Southwest and Southeast quadrants of the District of Columbia are included in the CG Overlay District: 601, 602, 603, 605, 607, 609, 611, 612, 613, 656, 657, 658, 660, 661, 662, E662, 664, E664, 665, 666, E667, S667, ES667, 698, 699, 700, 701, 702, 703, 704, 705, 706, 707, 708, E708, S708, 742, N743, S744, 769, 771, and 800, **as well as Square**

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649, Lot 48; Square 651, Lots 147 and 148; Square 653 Lots 14, 15, 52-54, 60-66, 68-72, 74, 75, 810, 811, 823, 824, 827 and 828; and Square 655 Lots 124-140.

B. Subsection 1602.1 (d) is amended to read as follows:

1602.1 Two (2) or more lots within the Overlay District may be combined for the purpose of allocating residential and nonresidential uses regardless of the normal limitation on floor area by uses on each lot; provided, that the aggregate residential and nonresidential floor area shall not exceed the matter-of-right maximum height or density of the underlying zone district(s), except when bonus density is being constructed, subject to the following:

- (d) The combined lot provisions may not be used to transfer density to or from any property within the CG/R-5-E, CG/C-2-C, CG/C-3-C, CG/W-1, CG/W-2, or CG/W-3 Districts; and

C. Section 1605, BUILDINGS, STRUCTURES, AND USES ON SOUTH CAPITOL STREET is amended to read as follows:

1605 BUILDINGS, STRUCTURES, AND USES ON SOUTH CAPITOL STREET

1605.1 The following provisions apply to new buildings, structures, or uses with frontage on South Capitol Street within the CG Overlay.

1605.2 Each new building or structure located on South Capitol Street shall be set back for its entire height and frontage not less than 15 feet, ~~provided that a minimum of 60% of the street wall shall be constructed on the setback line with the exception of:~~

- (a) A building within Squares 649 and 651; and
- (b) Replacement of an existing row dwelling building within Squares 653 or 655; or
- (c) A vertical addition to an existing row dwelling building within Squares 653 or 655, not extending out into the South Capitol Street right-of-way and not exceeding 50% of the gross floor area of the original row dwelling.

1605.3 Any portion of a building or structure that exceeds 110 feet in height shall provide an additional one-to-one (1:1) step back from the building line along South Capitol Street.

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1605.4 No private driveway may be constructed or used from South Capitol Street to any parking or loading berth areas in or adjacent to a building or structure constructed after February 16, 2007.

1605.5 For each new building or structure located on South Capitol Street, a minimum of 60% of the street-wall shall be constructed on the setback line, with the exception of:

- (a) Buildings within Squares 649 and 651 where a minimum of 60% of the street-wall shall be constructed to the South Capitol Street property line; and
- (b) Replacement of or an addition to an existing row dwelling within Squares 653 or 655 in accordance with §1605.2.

D. Section 1610, BUILDINGS, STRUCTURES, AND USES ON SOUTH CAPITOL STREET, is amended to read as follows:

1610.1 The following provisions apply to properties located:

- (a) Within the CG/W-2 District;
- (b) On a lot that abuts M Street SE;
- (c) On a lot located within Squares 700 or 701, north of the Ballpark site;
- (d) On a lot that abuts South Capitol Street, other than renovation or replacement of an existing row dwelling within Squares 653 or 655; or for a minor addition not exceeding 50% of the gross floor area of the original row dwelling structure;
- (e) On a lot within Square 601, 656, or 657; or
- (f) Any lot which is the recipient of density through the combined lot provisions of §1602.

All persons desiring to comment on the subject matter of this proposed rulemaking should file comments; in writing, to Sharon Schellin, Secretary to the Zoning Commission, Office of Zoning, 441 4th Street, N.W., Washington D.C. 20001. Comments must be received not later than thirty (30) days after the publication of this notice in the *D.C. Register*. A copy of this proposal may be obtained, at cost, by writing to the above address.